REMARKS

Claims 7-10 and 18 are pending in the present application. Claims 1-6, 11-17, and 19 are cancelled as being drawn to a non-elected invention. However, Applicants reserve the right to pursue these claims in separate Divisional Applications. In the Amendment herein, Applicants have amended the Claims to more clearly recite the invention. The changes made to the Claims and Specification by the current amendment, including ~~deletions~~ and additions, are shown in the respective sections above. No new matter has been added herewith. Entry of this Amendment and reconsideration of claims is requested.

Summary of the Interview

Applicants would like to thank the Examiner for the Interview of March 18, 2003. The contents of that interview are summarized as follows: The Applicant's representative showed immunocytographs from normal and AD blood samples. The AD samples had significantly more IRP-2 staining (green) then normal samples. The Examiner wanted a written explanation of the data and support for the claimed scope of the invention. More specifically, the Examiner wanted further information and evidence as to the following: which neurodegenerative diseases can the method be used for, what types of biological samples, how the Alzheimer's patients used for immunocytochemistry were diagnosed, and further data showing differential expression in Alzheimer's disease biological samples. All of this information is provided in the attached Declaration together with its Exhibits and the explanations provided hereinbelow.

Further, the Examiner wanted the preamble to be rewritten to more clearly fit the scope of the invention and to rewrite the claim to include reference to a control. The preamble has been written accordingly.

Support for the amendments to Claim 7

Support for "Parkinson's disease, Alzheimer's disease and MCI" can be found in the specification on page one lines 26-27, page x, lines x. Support for the " a biological sample having peripheral blood cells" can be found in the enclosed Declaration as well as the Specification page 7, lines 8 and 9. Support for SEQ ID NO:18 can be found in the specification page 8, line 20. Support for an "an amount significantly greater than that identified in a control sample" can be found in the Specification page 56, lines 17-20 and page 42, lines 28-31 as well as in the enclosed Declaration and data therein.

Rejection under 35 U.S.C.§112, first paragraph

Claims 7-10 are rejected under 35 U.S.C. .§112, first paragraph, as containing subject matter which was not enabled by the Specification. More specifically, the Examiner believed that there was no guidance in the Specification on how to detect IRP-2 in any biological sample, which can include saliva or urine. However, the claims have been amended to specify that the biological sample comprises peripheral blood cells, which is clearly enabled by the Specification.

The entire disclosure from page 29, line 16 to page 34, line 16 of the Specification is directed to a variety of different methods for detection of IRP-2 protein. In addition, the enclosed Declaration by Dr. Kirsch provides direct evidence that peripheral blood cells from a patient with MCI when treated with antibodies to IRP-2 showed a very different staining pattern as compared to a normal control.

Further, the Examiner believed that, although the association of brain iron regulation can be associated with Alzheimer's disease, there is no guidance in the Specification for association with all neurodegenerative diseases. However, the claims have been amended to specify Parkinson's disease, Alzheimer's disease and MCI. There is extensive guidance in the specification that the diagnosis of disease which involve abnormal iron accumulation in the brain can be identified using the antibodies and method disclosed. Further, the Declaration by Dr. Kirsch and the immunocytochemistry of Alzheimers disease provides direct evidence that MCI and Alzheimer's disease can be diagnosed using peripheral blood cells treated as claimed. Further the Declaration and enclosed references provide evidence that Parkinson's disease can be identified by the accumulation of iron due to the abnormal activity of IRP-2.

Rejection under 35 U.S.C.§112, second paragraph

Claims 7-10 are rejected under 35 U.S.C. .§112, second paragraph, as being indefinite for the following:

Claim 7 is believed indefinite for the recitation of IRP-2. Thus, as suggested by the Examiner, the full name has been included with the abbreviation in parenthesis and the SEQ ID NO: has been added.

Claim 7 is believed indefinite for the recitation of "a biological sample from [a] subject having polynucleotides or protein. Thus, the claim has been amended to read "a biological sample having peripheral blood cells from said subject, said sample having protein."

Claim 7 is believed indefinite because the recitation of "determining the presence or absence of the probe with the polynucleotide or protein in he biological sample" is not clear. Thus, the claim has been amended to read "determining the presence of an amount significantly greater than that identified in a control sample." , which Applicant submits is clear.

Claim 18 is believed indefinite because the Examiner believes the claim is unclear and needs to be rewritten. However, the claim has been cancelled.

As a result of the Amendments, Applicants believe the claims to be written in a clear fashion and respectfully request withdrawal of the rejection due to indefiniteness.

Conclusion

If any clarification is needed, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number appearing below

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 10, 2003

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